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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/656,589 | 09/04/2003 | Maury D. Cole | 113435-01 | 7922 |

27189 7590 11/13/2006

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EXAMINER

BRANDT, ADAM CURTIS

ART UNIT PAPER NUMBER

3771

DATE MAILED: 11/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/656,589

Applicant(s)

COLE, MAURY D.

Examiner

Adam Brandt

Art Unit

3743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6, 8-13, 15-20 and 22-25 is/are rejected.
- 7) ☒ Claim(s) 7, 14, 21, 26, 27 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12/9/03 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Specification

1. The disclosure is objected to because of the following informalities: the second flow meter/controller is numbered the same as the third flow meter/controller (252) (paragraph 0049). It is later mentioned in the specification the existence of a flow meter/controller referenced by the number 250.

Appropriate correction is required.

2. The use of the trademark Southco® has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Drawings

3. The drawings are objected to because the rubber gasket (180) is not identified in the figures. In addition, electrical line (256) is not identified in the figures. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as

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“amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

4. Claim 9 is objected to because of the following informalities: The first word of line 2 is typed as “at”, but the Examiner believes the Applicant meant “a”. Appropriate correction is required.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by Anderson et al. (6,776,158). Anderson discloses substance inhalation system, comprising:
a mixing flask (9);

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at least a first inhalation chamber (92) in fluid communication with the mixing flask;

at least a second inhalation chamber (92, col. 4, ln. 54-55, see figure 2) in fluid communication with the mixing flask;

a test vapor can be selectively and individually provided to the first inhalation chamber and the second inhalation chamber (col. 10, ln. 16-26; col. 4, ln. 40-47); and

the first inhalation chamber and the second inhalation platform can be selectively removed from the substance inhalation system without test vapor leaking therefrom (col. 4, ln. 40-47).

In regards to claim 2: Anderson discloses that the system is portable (col. 2, ln. 64-66).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35

U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. Claims 3, 5, 6, 8-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson et al. (6,776,158) in view of Leong (4,348,985).

Anderson discloses the portable system comprising the mixing flask (9), the first inhalation chamber (92), and the second inhalation chamber (90), but fails to mention that it can be placed on a cart. Leong teaches in figure 1 that it is well known in the art to place an animal inhalation system on a cart (11) with plural wheels (12) attached to the cart. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the portable inhalation system of Anderson by placing it on a cart with wheels so that it could more easily be moved from one location to another.

In regard to claim 5: Anderson discloses in column 4, lines 20-23 and that at least one test fluid reservoir in fluid communication with the mixing flask (9).

In regard to claim 6: Anderson discloses at least an air source (2) in fluid communication with the mixing flask (9) and air from the air source is mixed with a test fluid from the test fluid reservoir within the mixing flask (col. 4, ln. 12-24).

In regard to claim 8: Anderson discloses at least a first flow meter/controller (211;7;15) in fluid communication with the mixing flask (9) and the first inhalation chamber (92); at least a second flow meter/controller (211;7;15) in fluid communication with mixing flask (9) and the second inhalation chamber (92); the first flow meter/controller selectively controls the flow of test

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vapor the first inhalation chamber and the second flow meter/controller selectively controls the flow of test vapor to the second inhalation chamber.

In regard to claim 9: Anderson discloses in figure 8 a first inhalation chamber lid assembly(30,31,30,29a) enclosing the first inhalation chamber and a second inhalation chamber (30,31,30,29a) lid assembly enclosing the second inhalation chamber.

In regard to claim 10: Anderson discloses in figure 8 an inhalation chamber lid assembly with a lid plate (30;31); at least one disconnect fitting installed in the lid plate (23;24); the disconnect fitting includes a one-way valve incorporated therein (col. 3, ln. 1-2); a fluid line can be disconnected from the disconnect fitting without test vapor leaking from the disconnect fitting(col. 4, ln. 40-47).

10. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson et al. (6,776,158) in view of Leong (4,348,985) in view of King (2,141,794).

Anderson fails to disclose a heater thermally coupled to the mixing flask. King teaches that it well known in the art to have a heater (pg. 3, col. 1, ln. 3-10) thermally coupled to the mixing flask (B). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the system of Anderson with the heated mixing flask of King so that little variation in blood pressure and practically no excitation would occur in the lab animals.

11. Claims 11, 12, 13, 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson et al. (6,776,158) in view of Leong (4,348,985) in view of French (6,352,076).

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Anderson discloses a lid to an inhalation chamber but fails to disclose a latch that securely fastens the lid to the chamber assembly. French teaches that it is well known in the art to use latches on inhalation chambers (col. 4, ln. 6-8). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the inhalation chamber of Anderson to have latches as taught by French so that the potentially infectious lab animals cannot dislodge the lid and escape.

In regard to claim 12: Anderson discloses a lid to an inhalation chamber but fails to disclose a gasket placed between the inhalation chamber lid assembly and the inhalation chamber. French teaches that it is well known in the art to use gasket material on the lid of inhalation chamber (col. 4, ln. 10-18). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the inhalation chamber of Anderson to gasket material as taught by French so as to form an air tight seal between the inhalation lid assembly and the inhalation chamber.

In regard to claim 13: Anderson discloses a lid to an inhalation chamber but fails to disclose a rubber plug removable installed within the lid plate and the rubber plug is removable to provide an access port to the inhalation chamber. French teaches that it well known in the art to have a port that can be removably sealed with a plastic cap for selective access to the inhalation chamber (col. 4, ln. 36-43). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the inhalation system of Anderson with the

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inhalation port of French so that access can be acquired to the inhalation chamber without the removal of the lid assembly:

French discloses the removable plug in the inhalation system, except for that it is located in the lid and that it is made of rubber. It would have been obvious to one having ordinary skill in the art at the time the invention was made to locate the plug and opening in the lid, since it has been held that omission of an element and its function in a combination where the remaining elements perform the same functions as before involves only routine skill in the art. *In re Karlson*, 136 USPQ 184. Additionally, it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use. *In re Leshin*, 125 USPQ 416.

In regard to claim 15: Anderson discloses an inhalation chamber but fails to disclose a lid assembly with at least one divider extending from the lid plate into the inhalation chamber and that the divider divides the inhalation chamber into at least a first portion and at least a second portion; so that at least one test subject can be placed within the first portion of the inhalation chamber and at least one test subject can be placed within the second portion of the inhalation chamber. French teaches in figure 2 and column 5, lines 50-55 that it is well known in the art to have an inhalation chamber that is divided in two separated containers that which can both hold a different lab animals. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the inhalation chamber of Anderson with a dividing wall as taught by French so more lab animals can exposed to the test vapors in a controlled environment where they are not in direct physical contact with other lab animals.

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Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson et al.

(6,776,158) in view of Leong (4,348,985) in view of French (6,352,076) in view of Thomas (4,690,100).

Anderson discloses an inhalation system lid, but does not disclose a lid with at least a first and second water cup attached to a bottom surface of the lid plate and at least a first and second sipper tube extending from respective first and second water cups and that each water cup is located on an opposite side of the divider. Thomas teaches in figure 5 that it is well known to have a water bottle with sipper tube extending from said bottle suspended from the lid of the inhalation chamber in each animal confinement receptacle. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the inhalation system of Anderson with the water bottle holder located in each animal confinement receptacle as taught by Thomas so that the lab animals could easily access a water if they so wished it during an extended stay in the chamber.

12. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson et al. (6,776,158).

Anderson discloses in figure 8 an inhalation chamber lid assembly with a lid plate (30;31); at least one disconnect fitting installed in the lid plate (23;24); a fluid line can be disconnected from the disconnect fitting without test vapor leaking from the disconnect fitting(col. 4, ln. 40-47). It is obvious that any fluid line can be disconnected from the disconnect fitting without test vapor leaking if the vapor source has been removed or turned off. Therefore, the disconnect fitting can be considered to meet the limitations of the claims. Anderson discloses the disconnect fitting

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includes a one-way valve incorporated therein (col. 3, ln. 1-2) in-line with the solo apparatus, but fails to disclose that is in the disconnect fitting in the group inhalation chamber. It would have been obvious to one having ordinary skill in the art at the time the invention was made to place the one-way valve in the disconnect fitting on the lid plate of the inhalation chamber so that the vapors in the chamber could not escape through the fitting.

13. Claims 18-20, 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson et al. (6,776,158) in view of French (6,352,076).

Anderson discloses a lid to an inhalation chamber but fails to disclose a latch that securely fastens the lid to the chamber assembly. French teaches that it is well known in the art to use latches on inhalation chambers (col. 4, ln. 6-8). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the inhalation chamber of Anderson to have latches as taught by French so that the potentially infectious lab animals cannot dislodge the lid and escape.

In regard to claim 19: Anderson discloses a lid to an inhalation chamber but fails to disclose a gasket placed between the inhalation chamber lid assembly and the inhalation chamber. French teaches that it is well known in the art to use gasket material on the lid of inhalation chamber (col. 4, ln. 10-18). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the inhalation chamber of Anderson to gasket material as taught by French so as to form an air tight seal between the inhalation lid assembly and the inhalation chamber.

In regard to claim 20: Anderson discloses a lid to an inhalation chamber but fails to disclose a rubber plug removable installed within the lid plate and the rubber plug is removable to provide an access port to the inhalation chamber. French teaches that it well known in the art to have a port that can be removably sealed with a plastic cap for selective access to the inhalation chamber (col. 4, ln. 36-43). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the inhalation system of Anderson with the inhalation port of French so that access can be acquired to the inhalation chamber without the removal of the lid assembly.

French discloses the removable plug in the inhalation system, except for that it is located in the lid and that it is made of rubber. It would have been obvious to one having ordinary skill in the art at the time the invention was made to locate the plug and opening in the lid, since it has been held that omission of an element and its function in a combination where the remaining elements perform the same functions as before involves only routine skill in the art. *In re Karlson*, 136 USPQ 184. Additionally, it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use. *In re Leshin*, 125 USPQ 416.

In regard to claim 22: Anderson discloses an inhalation chamber but fails to disclose a lid assembly with at least one divider extending from the lid plate into the inhalation chamber and that the divider divides the inhalation chamber into at least a first portion and at least a second portion; so that at least one test subject can be placed within the first portion of the inhalation

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chamber and at least one test subject can be placed within the second portion of the inhalation chamber. French teaches in figure 2 and column 5, lines 50-55 that it is well known in the art to have an inhalation chamber that is divided in two separated containers that which can both hold a different lab animals. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the inhalation chamber of Anderson with a dividing wall as taught by French so more lab animals can exposed to the test vapors in a controlled environment where they are not in direct physical contact with other lab animals.

14. Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson et al. (6,776,158) in view of French (6,352,076) in view of Thomas (4,690,100).

Anderson discloses an inhalation system lid, but does not disclose a lid with at least a first and second water cup attached to a bottom surface of the lid plate and at least and first and second sipper tube extending from respective first and second water cups and that each water cup is located on an opposite side of the divider. Thomas teaches in figure 5 that it is well known to have a water bottle with sipper tube extending from said bottle suspended from the lid of the inhalation chamber in each animal confinement receptacle. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the inhalation system of Anderson with the water bottle holder located in each animal confinement receptacle as taught by Thomas so that the lab animals could easily access a water if they so wished it during an extended stay in the chamber.

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15. Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson et al. (6,776,158) in view of Wensly et al. (US 2003/0062042).

Anderson discloses substance inhalation system with mixing flask (9); a test fluid reservoir (anesthesia reservoir before entering mixing flask (9); col. 4, ln. 20-23) in fluid communication with the mixing flask; at least a first inhalation chamber (92) in fluid communication with the mixing flask; at least a second inhalation chamber (92, col. 4, ln. 54-55, see figure 2) in fluid communication with the mixing flask; at least a first flow meter/controller (211;7;15) in fluid communication with the mixing flask (9) and the first inhalation chamber (92); at least a second flow meter/controller (211;7;15) in fluid communication with mixing flask (9) and the second inhalation chamber (92). Anderson fails to disclose a microprocessor electrically connected to the first flow meter/controller and the second flow meter/controller, the microprocessor includes logic for selectively controlling the flow of test vapors to the first and second inhalation chambers. Wensley teaches that it is well known in the art to use flow meters (4) and controllers (30) electrically connected to a computer (20) containing a microprocessor to regulate the flow of gas to a patient. It would have been obvious to one having ordinary skill in the art at the time the invention was made program multiple flow sensors and controllers into the logic implemented by the microprocessor, since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis.*, 193 USPQ 8.

16. Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson et al. (6,776,158) in view of Wensly et al. (US 2003/0062042) in view of Lugtigheid et al. (6,158,434).

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Anderson discloses a inhalation system modified by Wensley that utilizes a microprocessor, but Anderson fails to disclose that the logic used for the microprocessor determines whether a test parameter is in a predetermined range and based in part on that parameter alters the flow of the test vapors to the inhalation chambers. Lugtigheid teaches in column 5, line 38-50 that it is well known in the art to implement an algorithm that controls the flow by using data collected by a flow meter and comparing it to a predetermined range. Lugtigheid teaches in column 4, lines 50-67 that alterations can then be made to control the flow of system based on the data collected. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use such a control algorithm to monitor the flow of the test vapors in the inhalation system so that control complexity is simple and adequately handles the responsibilities of required.

Allowable Subject Matter

17. Claims 7, 14, 21, 26, 27 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

18. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Quattrone et al. (3,367,308); Montgomery (3,537,428); Mosher (3,838,687); LaBauve (4,520,808); LoMaglio (4,526,133); Lattuada (4,593,650); Murray et al. (4,699,088);

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Pekovic (4,787,382); Anderson (4,941,431); Lomask (5,379,777); Coiro et al.
(5,400,744); Stout (3,464,388).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Adam Brandt whose telephone number is 571-272-7199. The examiner can normally be reached on 8:30 AM to 4:30 PM; Mon thru Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on 571-272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Adam Brandt
Examiner
Art Unit 3771

ACB



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11/9/06